



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 10/659,537 | 09/10/2003 | Deborah Ann Evrard | WYNC-0325 (AM101201NP) | 4846 |
| 38791 | 7590 | 02/09/2005 | | EXAMINER |
| WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103 | | | BERNHARDT, EMILY B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JL

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/659,537 | EVARD ET AL. | |
| | Examiner | Art Unit | |
| | Emily Bernhardt | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,7-10 and 49-52 is/are rejected.
- 7) Claim(s) 6 and 11-48 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/29/04 & 2/24/04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

The disclosure is objected to because of the following informalities: Parent history needs correction. See MPEP 1302.04 for claiming benefit of US provisional cases under 119(e). Applicants' format is directed to 120 benefit.

Appropriate correction is required.

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is outside the scope of claim 1 since benzodioxinyl is not a choice for "Ar" in claim 1.

Claims 1-5,7-10, and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specification provides no adequate support how to use **representative** scope of piperazines/azepines claimed which can carry a variety of tricyclic ring systems with varying Ar groups. While test data has been reported it is directed to tricyclic rings having for X-Y 2nd choice in claim 1. Within the data reported is much

evidence of structure-sensitivity. However, there is no reasonable assurance as to what other ring systems might work nor is there any basis in the prior art for assuming the other tricyclic choices are art-recognized equivalents for uses claimed herein. Receptor binding is known to be structure-sensitive in general.

Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group where as herein no examples of a diverse nature have been made much less tested showing the requisite activity needed to practice the invention. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition, which includes factors such as:

- 1) Breadth of the claims- the claims cover compounds easily in the millions as pointed out above;
- 2) Level of unpredictability in the art- the invention is pharmaceutical in nature involving inhibitory activity at a particular receptor (5-HT1A). It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally considered to be unpredictable. See In re Fisher 166 USPQ 18;

3) Direction or guidance- as stated above there are only 3 compounds actually made which are much closer to each other than to remaining scope ;

4) State of the prior art- The compounds are 1,4 diazines or diazepines with a certain substitution pattern at “X-Y” . No such compounds are known in the prior art having the instant activity.

5) Working examples- While test data has been presented the compounds are much closer to each other than to remaining scope.

In view of the above considerations, this rejection is being applied.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the uses embraced in 50 and 51, does not reasonably provide enablement for remaining uses covered in claim 49. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The only activity reported in the specification is for 5 HT1-A binding and a description of serotonin reuptake inhibition. The notion that simply having these activities will enable treatment of a whole class of disorders such as eating disorders, cocaine and alcohol addiction,etc. is not substantiated by the current state of the art. It is known that treating anxiety and depression can be accomplished by 5 HT1-A antagonists and known serotonin reuptake inhibitors

such as those mentioned on p.2 of the specification are useful for treating depression. See Robichaud provided with this action or the references cited by applicants in the IDS filed 1/29/04 which is directed to depression. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907. Note MPEP. 2164.05(a).

Claims 6, 11-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

References crossed out from the IDS of 1/29/04 cannot be considered unless copies of the reference(s) with pertinent pages are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Application/Control Number: 10/659,537
Art Unit: 1624

Page 6

E Bernhardt
Emily Bernhardt
Primary Examiner
Art Unit 1624